

K120407

APR 19 2012



EIZO NANA O CORPORATION, 153 Shimokashiwano, Hakusan, Ishikawa
924-8566 Japan

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Name Hiroaki Hashimoto
Department Medical System Standards

Telephone +81 (76) 274-2468
Fax +81 (76) 274-2484
E-Mail hiro@nanao.co.jp

Date February 6th, 2012

Traditional 510(k) Summary (in accordance with 21 CFR 807.92)

1. Date of Summary

February 6th, 2012

2. Company

EIZO NANA O CORPORATION
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan

3. Authorized Contact Person

Hiroaki Hashimoto

4. Device Information

- Trade Name/Model: RadiForce GX240
- Common Name: 2MP Monochrome LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device

- Monochrome LCD Monitor, RadiForce GS220 (K070131)

6. Device Description

The RadiForce GX240 is a monochrome LCD monitor for viewing medical images other than those of mammography. The matrix size (or resolution) of the panel is 1,200 x 1,600 pixels (2MP) with a pixel pitch of 0.270 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

Model variations with cosmetic differences are distinguished by characters attached to the name of the base model “GX240” such as “GX240-CL”, a model whose backlight is Clear Base (one of tints) although the hardware design, components and labeling remain unchanged.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including GX240 based on several QC guidelines. The RadiCS and its subset, RadiCS LE are included in this 510(k) submission as an accessory to the RadiForce GX240.

7. Intended Use

The RadiForce GX240 is intended to be used in displaying and viewing digital images by trained medical practitioners. The RadiForce GX240 does not support the display of mammography images for diagnosis.

8. Technological Characteristics

The RadiForce GX240 can be said to have at least the same display performances as those of the predicate device, RadiForce GS220 by default due to the following reasons:

- a. The matrix sizes (1,200 x 1,600) and the active area sizes (324.0 mm x 432.0 mm) of the LCD panels used by the both devices are the same.
- b. The DICOM calibrated luminance values of the both devices are the same (500 cd/m²) though the typical maximum luminance values (1,200 cd/m²) is higher than that of the predicate device (1,000 cd/m²). The higher luminance to be maintained constantly was realized by the employment of LED backlight deteriorating more slowly than conventional CCFL backlights.
- c. The LED backlight was newly employed instead of CCFL backlight because it is mercury-free, consumes less power and deteriorates more slowly. We have not recognized any adverse effects of the LED backlight on the quality of displayed images. Refer to section 18 “Performance Testing - Bench” where several image quality characteristics of the proposed device are compared with those of the predicate device.
- d. The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in lookup tables inside of them.
- e. As for input video signal, in addition to the Digital Visual Interface (DVI) also supported by the predicate device, RadiForce GX240 supports DisplayPort, another type of digital video interface based on an industrial standard. As far as the both the DVI and the DisplayPort are digital, their differences do not affect the quality of displayed images.

As for the maintenance, the same QC software is used for the both devices and the implementation of the Backlight Sensor (BS) stabilizing the backlight is also the same.

As for built-in sensors, in addition to BS common to the both devices, GX240 has three kinds of sensors. However, only the Built-in Front Sensor (IFS) has something to do with the maintenance or the calibration; the Presence Sensor (PS) detects the absence of the user to trigger the power saving mode of the monitor and the Ambient Light Sensor (ALS) is used to measure the ambient light by lx. The IFS enables automatic grayscale calibration by measuring

the luminance at the screen surface. Without IFS, the grayscale calibration process requires human intervention and the use of an external sensor. The accuracy data of the calibration with external sensors and that with the IFS is included in section 16.9 “Verification and Validation Documentation”.

9. Performance Testing

The following bench tests were performed on the RadiForce GX240:

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in the TG18 guideline
- The maximum number allowed for each type of pixel defects/faults agreed with the manufacturer from which Eizo buys the LCD panels for RadiForce GX240

The test results showed that the RadiForce GX240 has display performances substantially equivalence to those of the predicate device, RadiForce GS220. Besides, the display performances of the RadiForce GX240 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce GX240.

10. Conclusion

The 2MP Monochrome LCD Monitor, RadiForce GX240 is substantially equivalent to the predicate device with respect to technical characteristics, performance, application and intended use. The specifications of the primary component employed by the proposed device are the same as those of the predicate device and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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10903 New Hampshire Avenue
Document Control Room - WO66-G609
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Mr. Hiroaki Hashimoto
Regulatory Affairs Manager
EIZO NANA Corporation
153 Shimokashiwano
924-8566 HAKUSAN ISHIKAWA
JAPAN

APR 19 2012

Re: K120407

Trade/Device Name: 2MP Monochrome LCD Monitor, RadiForce GX240
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 6, 2012
Received: February 9, 2012

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

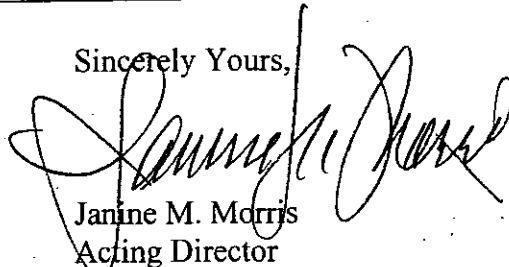
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: 2MP Monochrome LCD Monitor, RadiForce GX240

Indications for Use:

The RadiForce GX240 is intended to be used in displaying and viewing digital images by trained medical practitioners. The RadiForce GX240 does not support the display of mammography images for diagnosis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120407